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| 09/656,640      | 09/07/2000  | Huaming Wang         | GC584-2             | 1978             |

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GENENCOR INTERNATIONAL, INC.  
ATTENTION: LEGAL DEPARTMENT  
925 PAGE MILL ROAD  
PALO ALTO, CA 94304

EXAMINER

RAO, MANJUNATH N

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1652

DATE MAILED: 08/07/2003

20

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/656,640

Applicant(s)

WANG, HUAMING

Examiner

Manjunath N. Rao, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 1-11, 17 and 22-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-16 and 18-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 September 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4, 5. 6) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

Claims 1-24 are still at issue and are present for examination. Claims 12-16 and 18-21 are now under consideration. Claims 1-11, 17, 22-24 remain withdrawn from consideration as being drawn to non-elected invention.

#### ***Election/Restrictions***

Applicant's election of Group II and, amino acid position 254 as the species in Paper No. 15 and 18 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

#### ***Priority***

This application repeats a substantial portion of prior Application No. 09/401476, filed 9-22-1999, now US 6,168,936 B1, 1-2-01, and adds and claims additional disclosure not presented in the prior application. Since this application names an inventor or inventors named in the prior application, it may constitute a continuation-in-part of the prior application. Should applicant desire to obtain the benefit of the filing date of the prior application, attention is directed to 35 U.S.C. 120 and 37 CFR 1.78.

#### ***Drawings***

Drawings submitted in this application are accepted by the Examiner for examination purposes only.

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***Claim Objections***

Claims 12-16 are objected to because of the following informalities: Claim 12 and claims 13-16 which depend from claim 12, depends from a non-elected claim, claim 2.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 18 and claims 19-20 which depend therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 18 recites the phrase “derived from a *Stachybotrys* sp...”. The metes and bounds of this phrase is not clear to the Examiner. Literally, while the term “derive” means “to isolate from or obtain from a source”, the above term could also mean “to arrive at by reasoning i.e., to deduce or infer” or also as “to produce or obtain from another substance”. Therefore, it is not clear to the Examiner either from the specification or from the claims as to what applicants mean by the above phrase. It is not clear to the Examiner whether the “derived from *Stachybotrys*” encompasses a polypeptide as in “isolated from *Stachybotrys*” or whether it encompasses recombinants, variants and mutants of phenol oxidase of any from any other source and labeled as “derived from *Stachybotrys*”. As applicants have not provided a definition for the above phrase, Examiner has interpreted the claims broadly to mean, that a the phrase encompasses sequences which are recombinants,

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variants, or mutants of any phenol oxidase. Examiner has given the same interpretation while considering the claims for all other rejections.

Claim 18 and claims 19-20 which depend therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 18 recites the phrase "altered property". The metes and bounds of the above phrase is not clear to the Examiner. It is not clear to the Examiner as to what change or changes are encompassed in the phrase "altered property". A perusal of the specification did not yield a specific definition for the above phrase thus rendering the claim indefinite.

Claims 18, 21 and claims 19-20 which depend therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 18, 21 recite the phrase "precursor phenol oxidizing enzyme" or "precursor enzyme". The metes and bounds of the term "precursor" is not clear to the Examiner. It is not clear to the Examiner as to whether applicants are claiming a unprocessed enzyme, i.e., still comprising the signal peptide or whether it refers to the substrate of the enzyme.

Claim 18 and claims 19-20 which depend therefrom are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 18 recites the phrase "increased

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phenol oxidizing activity" and "increased pH optimum". The metes and bounds of the above phrase is not clear to the Examiner. It is not clear to the Examiner as to how much of a change in activity or pH optimum is considered to be "increased" and with reference to which other enzyme. Without such information the claim is rendered indefinite.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 12-16 and 18-21 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 5-14 of U.S. Patent No. 6,168,936.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim, because the examined claim is either anticipated by, or would have been obvious over the reference claim. See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi* 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 12-16 and 18-21 of the instant application are

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directed to variants of phenol-oxidase enzyme having an amino acid sequence that is at least 68% identical to SEQ ID NO:2, wherein the variant enzyme differs from the enzyme with SEQ ID NO:2 in that the elected amino acid position 254 has a different amino acid. Claims are also drawn to method of making the variant enzyme by culturing host cells transformed with mutagenized polynucleotide encoding SEQ ID NO:2 such that the encoded mutagenized enzyme has an increase in activity and optimum pH values and the encoding polynucleotide hybridizes to the polynucleotide encoding SEQ ID NO:2 under medium to high stringency.

The specification (and the claims) of the reference patent already teaches phenol oxidizing enzyme that is at least 68% identical to SEQ ID NO:2 and polynucleotides encoding the same. The reference also teaches vectors and host cells for expressing said polynucleotides. The specification also teaches that such phenol-oxidizing enzymes can be used in detergent compositions and thus have commercial value and that there is also a need for enzymes which have a higher pH optimum and a higher activity levels.

Claims 12-16 and 18-21 cannot be considered patentably distinct over claims 1, 5-14 of the reference patent when there is specifically disclosed embodiment in the reference patent that supports claims 1, 5-14 of that patent and falls within the scope of claims 12-16 and 18-21 herein because it would have been obvious to one having ordinary skill in the art to modify claims 1, 5-14 of the reference by selecting a specifically disclosed embodiment that supports those claims i.e., a variant of a parent phenol-oxidase that is 68% identical to SEQ ID NO:2, wherein there is a specific change at amino acid position 254.

Therefore, it would have been obvious to one of ordinary skill in the art to use the teachings from the above patent and subject the polynucleotide encoding the polypeptide that is

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at least 68% identical to SEQ ID NO:2 to random mutagenesis techniques that are well known and available in the art and isolate a specific mutant that has increased activity and pH optimum, wherein said variant has a specific change in amino acid at position 254 and arrive at the instant invention. One of ordinary skill in the art would have been motivated to do so as the reference patent teaches that phenol-oxidases are in great demand in the detergent industry and there is a need for enzymes with higher activity and pH optimum. One of ordinary skill in the art would have a reasonable expectation of success since the above patent provides the polynucleotide and the art provides a general technique for mutagenizing polynucleotides and arriving at mutants. Therefore the above invention would have been *prima facie* obvious to one of ordinary skill in the art.

### ***Conclusion***

None of the claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manjunath Rao whose telephone number is (703) 306-5681. The Examiner can normally be reached on M-F from 7:30 a.m. to 4:00 p.m. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, P.Achutamurthy, can be reached on (703) 308-3804. The fax number for Official Papers to Technology Center 1600 is (703) 305-3014.

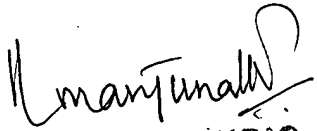


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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

  
MANJUNATH RAO  
PATENT EXAMINER

Manjunath N. Rao. Ph.D.  
August 5, 2003